



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

CUNNINGHAM *et al.*

Serial No. 09/954,695

Filed: September 11, 2001

For: COMPOSITIONS, METHODS AND KITS)
FOR DETERMINING THE PRESENCE)
OF CRYPTOSPORIDIUM ORGANISMS)
IN A TEST SAMPLE)

Group Art Unit: To Be Assigned

Examiner: To Be Assigned

Atty. Docket No. GP116-02.UT

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**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97(b) & (c)**

Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants bring to the Examiner's attention the references listed on the enclosed form PTO/SB/08 (two copies) for consideration in connection with the examination of the above-identified application. A copy of each cited reference is enclosed herewith.

This Information Disclosure Statement is being submitted under 37 C.F.R. § 1.97(b) before the mailing date of a first Office action on the merits.

If Applicants are mistaken, and a first Office action on the merits was mailed on or before the certified date of mailing indicated below, then Applicants request that this Information Disclosure Statement be treated as a submission under 37 C.F.R. § 1.97(c) and that the fee due under 37 C.F.R. § 1.17(p) be charged to Deposit Account No. 07-0835 in the name of Gen-Probe

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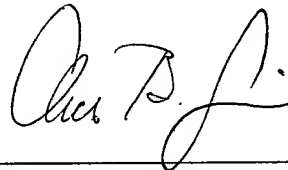
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Applicants respectfully request that the Examiner indicate consideration of each cited reference by returning a copy of the enclosed form PTO/SB/08 with the Examiner's initials or other appropriate marks.

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date indicated below with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

Respectfully Submitted,



Date: January 4, 2002

By: _____

Charles B. Cappellari
Registration No. 40,937
Attorney for Applicants

GEN-PROBE INCORPORATED
Patent Department
10210 Genetic Center Drive
San Diego, California 92121
PH: (858) 410-8927
FAX: (858) 410-8928

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Application Number	09/954,695
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Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	GP116-02.UT

Sheet	1	of	4
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Attorney Docket Number | **GP116-02.UT**

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		4851330	A	Kohne	07-25-1989	
		5030557	A	Hogan et al.	07-09-1991	
		5399491	A	Kacian et al.	03-21-1995	
		5539082	A	Nielsen et al.	07-23-1996	
		5556774	A	Wiedenmann et al.	09-17-1996	
		5591434	A	Jenkins et al.	01-07-1997	
		5690825	A	Parton	11-25-1997	
		5693472	A	Steele et al.	12-02-1997	
		5770368	A	De Leon et al.	06-23-1998	
		5789190	A	Crabb et al.	08-04-1998	
		5820767	A	Kane et al.	10-13-1998	
		5840488	A	Hogan	11-24-1998	
		5925517	A	Tyagi et al.	07-20-1999	
		6054279	A	Nadeau et al.	04-25-2000	
		6130038	A	Becker et al.	10-10-2000	
		6146838	A	Williams et al.	11-14-2000	

Examiner Initials ²	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
		EP	0652974	B1	Minister of Agr., Fisheries & Food of the U.K.	05-17-1995		
		WO	9402635	A1	Minister of Agr., Fisheries & Food of the U.K.	02-03-1994		
		WO	9404681	A1	Istituto Superiore Di Sanita et al.	03-03-1994		
		WO	9634978	A1	MacQuarie Research Limited et al.	11-07-1996		
		WO	9640926	A2	The Board of Regents of the University of Oklahoma	12-19-1996		
		WO	9702281	A1	Murdoch University	01-23-1997		
		WO	9703362	A1	ImmuCell Corporation	01-30-1997		
		WO	9708204	A1	MacQuarie Research Ltd et al.	03-06-1997		
		WO	9742349	A1	Metropolitan Water District of Southern California	11-13-1997		
		WO	9804675	A2	Pall Corporation	02-05-1998		

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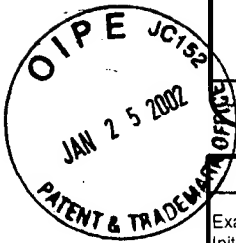
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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		AWAD-EL-KARIEM et al., "Detection and species identification of Cryptosporidium oocysts using a system based on PCR and endonuclease restriction", Parasitology, July 1994, p. 19-22, vol. 109, Cambridge University Press, UK	
		BALATBAT et al., "Detection of Cryptosporidium parvum DNA in Human Feces by Nested PCR", J. Clin. Microbiol., July 1996, p. 1769-1772, vol. 34, no. 7, American Society of Microbiology, US	
		CARRAWAY et al., "Genetic Markers Differentiate C. parvum Isolates", J. Eukaryot. Microbiol., Sept.-Oct. 1994, p. 26S, vol. 41, no. 5, Allen Press Inc., US	
		CHRISP et al., "Similarities and differences between DNA of cryptosporidium parvum and C. wrairi detected by the polymerase chain reaction", Folia Parasitol., 1994, p. 97-100, vol. 41, no. 2, Czech Academy of Sciences, CZ	
		DEERE et al., "Rapid method for fluorescent in situ ribosomal rna labeling of cryptosporidium parvum", J. Appl. Microbiol., Nov. 1998, p. 807-818, vol. 85, no. 5, Blackwell Science Limited, UK	
		GARCIA et al., "Detection of Microsporidial Spores in Fecal Specimens from Patients Diagnosed with Cryptosporidiosis", J. Clin. Microbiol., July 1994, p. 1739-1741, vol. 32, no. 7, American Society of Microbiology, US	
		KILANI et al., "Geographical Variation in 18S rRNA Gene Sequence of Cryptosporidium Parvum", Int. J. Parasitol., April 1994, p. 303-306, vol. 24, no. 2, Elsevier Science Limited, UK	
		LAXER et al., "DNA Sequences for the Specific Detection of Cryptosporidium Parvum by the Polymerase Chain Reaction" Am. J. Trop. Med. Hyg., Dec. 1991, p. 688-694, vol. 45, no. 6, Allen Press Incorporated, US	
		LINDQUIST et al., "Criteria for evaluation of proposed protozoan detection methods", J. Microbiol. Methods, July 1999, p. 33-43, vol. 37, no. 1, Elsevier Science Publishers BV, NE	
		LONG et al., "The Diagnosis of Old and New Gastrointestinal Parasites", Clin. Lab. Med., June 1995, p. 307-331, vol. 15, no. 2, W B Saunders Company, US	
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		MORGAN et al., "Differentiation Between Human and Animal Isolates of Cryptosporidium Parvum Using rDNA Sequencing and Direct PCR Analysis", J. Parasitol., Oct. 1997, p. 825-830, vol. 83, no. 5, American Society of Parasitologists, US	

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		MORGAN et al., "Phylogenetic Analysis of Cryptosporidium Isolates from Captive Reptiles Using 18S rDNA Sequence Data and Random Amplified Polymorphic DNA Analysis", J. Parasitol., June 1999, p. 525-530, vol. 85, no. 3, American Society of Parasitologists, US	
		ROCHELLE et al., "Development of a Rapid Detection Procedure for Cryptosporidium, Using In Vitro Cell Culture Combined with PCR", J. Eukaryot. Microbiol., Sept.-Oct. 1996, p. 72S, vol. 43, no.5, Allen Press, Inc., US	
		SHEPHERD et al., "An Evaluation of Methods for the Simultaneous Detection of Cryptosporidium Oocysts and Giardia Cysts from Water", Appl. Environ. Microbiol., Apr. 1996, p. 1317-1322, vol. 62, no. 4, American Society for Microbiology, US	
		SINGH, "Molecular Methods for Diagnosis and Epidemiological Studies of Parasitic Infections", Int. J. Parasitol., Oct. 1997, p. 1135-1145, vol. 27, no. 10, Elsevier Science Limited, UK	
		SLIFKO et al., "An In Vitro Method for Detecting Infectious Cryptosporidium Oocysts with Cell Culture", Appl. Environ. Microbiol., Sept. 1997, p. 3669-3675, vol. 63, no. 9, American Society for Microbiology, US	
		VESEY et al., "The use of a ribosomal RNA targeted oligonucleotide probe for fluorescent labelling of viable Cryptosporidium parvum oocysts", J. Appl. Microbiol., Sept. 1998, p. 429-440, vol. 85, no. 3, Blackwell Science Limited, UK	
		WEBSTER et al., "Detection of Cryptosporidium parvum using a specific polymerase chain reaction" Vet. Parasitol., Oct. 1993, p. 35-44, vol. 50, no. 1-2, Elsevier Science Publishers BV, NE	
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		XIAO et al., "Phylogenetic Analysis of Cryptosporidium Parasites Based on the Small-Subunit rRNA Gene Locus", Appl. Environ. Microbiol., Apr. 1999, p. 1578-1583, vol. 65, no. 4, American Society for Microbiology, US	
		ZHU et al., "Direct Isolation of DNA from Patient Stools for Polymerase Chain Reaction Detection of Cryptosporidium parvum", J. Infect. Dis., May 1998, p. 1443-1446, vol. 177, no. 5, University of Chicago Press, US	

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